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The purpose of this amendment is to initiate Work Assignment (WA) 3-02. Michael Pease is appointed as the work assignment manager (WAM). The Level of Efforts, (LOE) is in the amount of 634 hours. The statement of work is attached. The contractor shall submit a work plan and cost estimate as it relates to this request.											
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CONTRACT NAME: ERAS Analytical Support Contract Industrial Economics, Incorporated

CONTRACT NO. EPW - 12-013

Work Assignment No. WA - 3 - 2

Work Assignment

Manager: Michael Pease

Office of Resource Conservation and Recovery

MC 5303P

1200 Pennsylvania Ave, NW Washington, DC 20460 Phone: (703) 308-0008

TITLE: Financial Analysis Support for 108(b) Rulemaking

BACKGROUND

EPA is currently undertaking a rulemaking under CERCLA 108(b) which would require certain classes of facilities to post financial assurance for their liabilities associated with the production, treatment, storage and disposal of hazardous substances. (See 74 FR 37213 July 28, 2009 and 75 FR 816 January 6, 2010.) This rulemaking involves multiple financial analyses to be conducted to analyze rule options. Under a previous contract (EP-W-07-011), the contractor provided analyses involving the construction and evaluation of financial tests using credit ratings, financial statements and ratio analyses for hardrock mines and processors. At present, preliminary analyses have been conducted for both the extraction (mining) and processing portions of the potentially regulated universe and a draft background document created.

Under previous work assignments (WA-B2, 1-2 and 2-2) under this contract the contractor has evaluated potentially regulated companies' bankruptcy potential, prepared reports on historic rates of returns of various asset classes, built a model that simulates trust fund performance under various scenarios and has conducted initial monte carlo simulations evaluating the impact of certain variables on trust performance. The contractor has also collected updated data (FY13) for the corporate entities and key inputs of the financial test analysis and done some preliminary analysis of that data. The financial test analysis and background document will help the Agency make important policy decisions about whether and in what form a financial test should be allowed in the regulations and document the work done. The information on asset returns, the trust performance model and the monte carlo simulation analyses will help EPA evaluate and inform options for the selection of a discount rate.

PURPOSE AND OBJECTIVES

This work assignment intends to accomplish several objectives in support of the CERCLA 108(b) rule writing initiative. First, it will continue supporting the evaluation of financial tests as a method of self-insurance for the hardrock mining sector and finish the production of a background document that explains the analyses conducted and the results. (task 2). Second, it will continue to evaluate possible discount rates and trust management approaches for possible application in funding long term obligations in the proposed regulations (task 3).

At present the Agency is prioritizing the updates to the financial test analysis. A draft of the financial test analysis has been conducted and new data has been collected but the analysis may also need to be refined or revised before the background document describing the analysis and findings can be finalized. The evaluation of discount rates and the analysis of trust fund performance will continue as the Agency's understanding of how financial assurance amounts will be determined comes into greater clarity.

Task 1: Work Plan and Management

Within three days after the Work Assignment is provided, but prior to preparing the Work Plan or initiating any other task, the contractor shall discuss with the EPA WAM via telephone conference call the background and intent of the task and deliverables.

Within 20 days of receipt of this Work Assignment, the contractor shall prepare and submit a work plan, staffing plan, and budget. The work plan shall lay out cost and labor hour estimates by task. In staffing this work the contractor shall include management with experience with financial test analysis, the treatment of environmental obligations in bankruptcy and the operation of financial responsibility programs and knowledge of discount rate theories and applications. The contractor will also conduct general management activities under this task. These activities shall include such efforts as project financial administration, periodic participation in conference calls and/or meeting with the EPA WAM, preparation of monthly progress reports, contract administration and management efforts. The contractor shall also provide updates on the status of each task to the EPA WAM via telephone conversations at least weekly.

In addition to the other requirements for the work plan, approval of the work plan for this assignment will be contingent upon the contractor providing the basis for how Contract Management Costs will be calculated and reflected on each month's invoice.

The Contractor shall describe in the work plan, how the Contractor plans to apply quality assurance (QA), and indicate in the work plan that the Contractor shall include a brief (e.g., one paragraph or less) summary of QA activities in the monthly progress/invoice reports to the WAM for this work assignment. Because the types of "data" involved in this SOW may mostly come from existing secondary sources which have already been subject to QA (e.g., peer-reviewed journals, audited financial statements and other Federal agencies such as the Securities Exchange Commission or the Mine Safety and Health Administration), the QA activities for this SOW may only require the Contractor to (a) examine data, calculations, and calculation results (e.g., evaluate numerical outliers), and (b) double-check spreadsheet calculation formulae.

Task 2: Continue Work on Financial Tests for Hardrock Mining

Financial test analyses for hardrock mining and processing facilities. Under a previous contract (EP-W-07-011), EPA acquired financial information on hardrock mining and processing facilities (as well as chemical manufacturing, petroleum refining and coal fired power plant facilities). Under this contract's WA 2-2, the contractor gathered updated financial information for the analysis and ran preliminary analyses of that data.

- A. Under this task the contractor shall refine financial test analyses of the hardrock mining processing and extraction companies as necessary, and integrate the analyses to show aggregate results. Alternatives considered in these analyses shall include the alternatives previously investigated for hardrock mining companies under the previous contract. Task 2A may involve analysis of additional provisions to the financial test proposal (e.g. a coverage multiple requirement analogous to that found at 40 CFR 264.143(f)(1)(i)(B) and (ii)(B)) or provisions in other financial assurance programs or consent decrees.
- B. Additional technical reports, analysis, and briefings on financial tests. During Agency and interagency review of products by the contractor, additional reports and briefings may be necessary. The contractor shall, for budget purposes, plan on two papers of 5 to 10 pages in length and one briefing. The topics will be described by the WAM in technical directives.
- C. Finalize Background Documents for Hardrock Mining Rule Financial Test Proposal. Under a previous contract the contractor prepared a draft background document for the hardrock mining extraction universe. Under Task 2 C of this work assignment the contractor will update the background document to reflect any changes in the analyses that result from tasks 2A or B of this work assignment and the new data collected and then finalize the background document. The background document should cover the hardrock mining extraction and processing universe and provide information for the proposal on the information supporting the analyses, the methodologies followed, and the results of the analyses. The results should be shown for processing and extraction separately and integrated. This document should follow the same outline as the draft background document prepared for the hardrock mining extraction universe of facilities. WAM comments on the background document shall be incorporated and revised drafts of the document prepared as necessary.

Task 3: Analysis of Discount Rates and Trust Management for Funding Long Term Remediation Costs.

As part of the proposed rule the Agency may allow trust funds (either standby in conjunction with a third party instrument or funded) be used to secure funds for long term obligations. Further, funds, at times, may be recovered and placed in the Superfund while long-term work is underway at a site. The initial funding amount, and the manner in which trusts are managed and invested can affect the amount of funds available for remediation work in the future. Additionally, investment strategies and returns may inform the discount rate chosen for long term obligations. For example, the Agency may allow the series of expected future payments required to fund long term water treatment at a site to be discounted at a rate reflective of projected investment returns to arrive at a present value amount. The selected discount rate

may greatly affect the cost to industry of complying with the regulation and the likelihood that funds are available to meet future environmental costs, and thus public costs.

- A. The contractor may be asked to refine the model of trust fund performance and the initial monte carlo simulation analyses prepared under the previous work assignment (WA 1-2). Areas of possible refinement may be adjustments necessary to allow for the use of the analytical results in the public domain or to allow for trust model to be more easily updated by EPA in the future.
- B. In addition, the contractor shall continue to analyze various discount rates or information related to discount rates to assess the costs to industry arising from a given rate and the potential costs to the government at a given rate. The analysis should show the risk to the government at each rate and the variation in costs to industry at each rate.
- C. The contractor shall also revise the analyses in Task 2 A and/or B in response to workgroup or stakeholder comments as directed by the WAM.

Deliverable	Due date
Task 1: Work Plan and Management	
Telephone Discussion w/WAM	Within three days of work assignment initiation
Workplan, staffing and budget	Within 20 days of issuance of the work assignment
Task 2 Continue Work on Financial	
Tests for Hardrock Mining	
A. Financial test analyses of the	Refinements reflecting new data and WAM input
hardrock mining extraction and	June 12, 2015
processing facilities refinements	Revised report 2 weeks after WAM comments
B. Additional technical reports,	TBD based on TD from WAM
analysis, and briefings on financial	
tests	
C. Update, revise and finalize	TBD based on TD from WAM
background documents for HRM	Revised report three weeks after receipt of WAM
financial test proposal	comments
Task 3: Discount Rate Analyses	
A. Trust fund performance	Revised report three weeks after receipt of TD from
modeling	WAM
B. Discount rate analyses	Initial analysis due Dec 10, 2015
	Revised report two weeks after receipt of WAM
	comments

C. Revisions to analyses in	TBD based on TD of WAM
response to workgroup	Revised reports two weeks after receipt of WAM
comment	comments.

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Comments: The purpose of this amendment is to initiate Work Assignment(WA) 3-4. Rachel Horton is appointed as the work assignment manager (WAM) and Scott Palmer as appointed the alternate. WAM. The Level of Effort (LOE) is in the amount of 292 hours. The statement of work is attached. The contractor shall submit a work plan and cost estimate as it relates to this request.											he		
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Statement of Work

Work Assignment Number: 3-4

Title: Preparation of Regulatory Impact Analysis for Pharmaceuticals, and Related Work

Contracting Officer's Representative (COR): Rachel Alford

Alternate COR: Scott Palmer

Address: OSWER/ORCR/ERAS

Mail Code: 5305P

1200 Pennsylvania Ave., NW Washington, D.C. 20460

Telephone: (703) 305-0894

(703) 308-8895 (front office) (703) 308-7903 (FAX)

BACKGROUND:

In December 2008, EPA proposed to add hazardous pharmaceutical wastes to the current federal Universal Waste (UW) Program. The UW Program is a set of simplified hazardous waste management standards for a small group of hazardous wastes which currently include batteries, pesticides, lamps and mercury-containing equipment. UWs are typically low-risk during accumulation and transport and are generated in a variety of settings other than the industrial setting (e.g., retail stores, office buildings households). EPA believed that adding hazardous waste pharmaceuticals to the UW program would have simplified the management of hazardous waste pharmaceuticals for the health care industry while encouraging proper disposal of hazardous waste pharmaceuticals. However, based on the public comments received on the proposal, particularly comments raising concerns over the diversion of such wastes due to the lack of notification and manifest requirements under the universal waste program, EPA has decided that the Universal Waste Rule is not the appropriate regulatory approach to address the management of hazardous waste pharmaceuticals. Therefore EPA is working on a new Proposed Pharmaceuticals Rule that will be under a different, more comprehensive regulatory approach.

The EPA has collected data on the amount of pharmaceuticals generated at different facilities, as well as completed a draft Regulatory Impact Analysis.

PURPOSE AND SCOPE OF THIS WORK STATEMENT:

The purpose of the Statement of Work is to provide for all analytical assessment needs related to costs, economic impacts, benefits, document preparation, and related technical and supporting analyses necessary to support the Agency's promulgation of the proposed rule: Pharmaceuticals ORCR Rule. The scope of the Statement of Work includes refinement of cost-benefit analysis based on workgroup, OP and OMB review, and assistance to the COR to respond to analytical comments and questions from the Office of Policy (OP) and Office of Management Budget (OMB). The contractor shall make the best use possible of the Regulatory Impact Analysis (RIA) also known as a Economic Analysis (EA)¹ completed on November 3, 2014 prepared for the proposed rule under contract EP-W-12-013 WA 2-04. The contractor shall not duplicate work done under previous Work Assignments.

Task 1: Submit Work Plan & Budget

The contractor shall supply the COR with a proposed work plan, deliverables schedule, and cost estimate for completing the Tasks described in this SOW. For each of the Tasks in this SOW which involves "environmental data" --- as defined according to EPA's mandatory quality management system² --- the Contractor shall describe in the work plan, how the Contractor plans to apply quality assurance (QA), and indicate in the work plan that the Contractor shall include a brief (e.g., one paragraph or less) summary of QA activities in the monthly progress/invoice reports to the WAM for this work assignment. Because the types of "environmental data" involved in this SOW may mostly come from existing secondary sources which have already been subject to QA (e.g., peer-reviewed journals, and other Federal agencies such as the Energy Information Administration, the Census Bureau, and the Bureau of Labor Statistics), the QA activities for this SOW may only require the Contractor to (a) examine data, calculations, and calculation results (e.g., evaluate numerical outliers), and (b) double-check spreadsheet calculation formulae.

Task 1 Deliverable:

Proposed work plan, deliverables schedule, and cost estimate (budget).

Task 2: Respond to OP and OMB Comments and Revise the RIA

The contractor shall respond to workgroup and OMB comments and revise the RIA based on direction from the WAM. The contractor shall if asked assist with briefing presentations and make editorial and numerical changes to the RIA based on OMB comments. The contractor shall assist with the finalization of the November 3, 2014 draft RIA entitled Regulatory Impact Analysis for EPA's proposed Healthcare Facility-specific Regulations for the Management of Hazardous Waste Pharmaceuticals. The contractor shall revise the RIA in response to workgroup, WAM and OMB comments. There may be editorial comments as well as a need for

¹ The RIA is a required cost and benefit analysis document for EPA's regulations.

Additional information about EPA's quality management system is available at http://www.epa.gov/quality/

revisions to the methodology and/or numbers in the RIA. Occasionally OMB requests additional sensitivity analysis. The contractor may also be asked to provide briefing materials for OMB and EPA meetings.

These activities may include, but are not necessarily limited to:

- Additional analyses of the methodology and the models employed in the EA;
- Sensitivity analysis of the number of entities, costs, and/or benefits;
- Preparing briefing packages;
- Providing tables, bullet lists, fact sheets, flow charts, or presentation graphics;
- Drafting a short memo in response to OMB comments regarding how their comments will be handled in regard to the final EA; and
- Incorporating editorial comments into the final EA.

Task 2: Deliverables

The deliverable under this Task shall be draft and final versions of the completed RIA. The draft deliverable shall be due within 10 working days from COR receipt of the final deliverable (TD or otherwise) under Task 2. The final deliverable shall be due no later than five working days following contractor receipt of all written COR comments on the draft. Briefing packages shall be prepared within 2 Agency work days and e-mailed to the WAM and alternate-WAM.

Task 3: Respond to Public Comments on the RIA

The contractor shall respond to public comments on the Pharmaceuticals Rule RIA in a Memorandum. The contractor shall finalize responses to public comments on the Pharmaceuticals Rule RIA according to WAM direction. The contractor shall provide brief responses in "plain English" to public comments.

- The contractor shall create a way to organize public RIA comments and contractor responses by RIA topic headings.
- The contractor will provide responses to all RIA comments and provide a draft to the WAM.

Task 3: Deliverables

The deliverable under this Task shall be draft and final versions of response to comments Pharmaceuticals RIA Memorandum. The draft deliverable shall be due within 20 working days from COR receipt of the final deliverable (TD or otherwise) under Task 3. The final deliverable

shall be due no later than 10 working days following contractor receipt of all written COR comments on the draft.

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Statement of Work

Work Assignment Number: 3-4

Title: Preparation of Regulatory Impact Analysis for Pharmaceuticals, and Related Work

Contracting Officer's Representative (COR): Rachel Horton

Alternate COR: Chris McMinimy

Address: OSWER/ORCR/ERAS

Mail Code: 5305P

1200 Pennsylvania Ave., NW Washington, D.C. 20460

Telephone: (703) 305-0894

(703) 308-8895 (front office) (703) 308-7903 (FAX)

BACKGROUND:

On September 15, 2015 the EPA published and put out for public comments the Management Standards for Hazardous Waste Pharmaceuticals Proposed Rule and Supporting Regulatory Impact Analysis (RIA). Industrial Economics Inc (IEc) help develop and write the supporting RIA and is now tasked with collecting and updating the supporting data for the final pharmaceuticals rule RIA, making changes and revisions to the rule RIA based on public, workgroup comments, Office Of Policy (OP) and the Office of Management and Budget (OMB) comments, updating the benefits of the RIA for the final rule and refining the costs based on any regulatory changes from the proposed rule to the final pharmaceuticals rule. Because the final rule is on a quick timeline the contractor shall help plan and commence the collecting of supporting data, updating exhibits in the universe chapter 2, any Executive Orders supporting data information and other tasks as needed so when option selections and regulatory details are provided the final pharmaceuticals rule draft RIA can be completed as quickly as possible while still responding to public and workgroup comments. I have attached the current draft regulatory schedule as Attachment A to the Work Assignment. This schedule is subject to change, however, the rule schedule is an indication of the potential tight timelines the final pharmaceuticals rule may be held to.

PURPOSE AND SCOPE OF THIS WORK STATEMENT:

The purpose of the Statement of Work is to provide for all analytical assessment needs related to costs, economic impacts, benefits, document preparation, and related technical and supporting analyses necessary to support the Agency's promulgation of the final rule: Pharmaceuticals

ORCR Rule. The scope of the Statement of Work includes refinement of cost-benefit analysis based on workgroup, public comments and assistance to the COR to respond to analytical comments and questions from the Office of Policy (OP) and Office of Management Budget (OMB). The contractor shall make the best use possible of the Regulatory Impact Analysis (RIA) also known as an Economic Analysis (EA)¹ completed and published in the Federal Register on September 15, 2015 prepared for the proposed rule under contract EP-W-12-013 WA 3-04. The contractor shall not duplicate work done under previous Work Assignments.

Task 1: Submit Work Plan & Budget

The contractor shall supply the COR with a proposed work plan, deliverables schedule, and cost estimate for completing the Tasks described in this SOW. For each of the Tasks in this SOW which involves "environmental data" --- as defined according to EPA's mandatory quality management system² --- the Contractor shall describe in the work plan, how the Contractor plans to apply quality assurance (QA), and indicate in the work plan that the Contractor shall include a brief (e.g., one paragraph or less) summary of QA activities in the monthly progress/invoice reports to the WAM for this work assignment. Because the types of "environmental data" involved in this SOW may mostly come from existing secondary sources which have already been subject to QA (e.g., peer-reviewed journals, and other Federal agencies such as the Energy Information Administration, the Census Bureau, and the Bureau of Labor Statistics), the QA activities for this SOW may only require the Contractor to (a) examine data, calculations, and calculation results (e.g., evaluate numerical outliers), and (b) double-check spreadsheet calculation formulae.

Task 1 Deliverable:

Proposed work plan, deliverables schedule, and cost estimate (budget).

Task 2: Collect data and Update the Universe of Facilities to Be Regulated under the Final Pharmaceuticals Rule

The contractor shall utilize the updated RCRA Info and Biennial Report (BR) Data from the hazardous waste generators rule under contract EP-W-12-013 and Statement of Work (SOW) number 3-8 and collect any additional data needed for the pharmaceuticals final rule for the NAICS codes in the regulated universe described in Exhibit ES-1 entitled Number of Large Quantity Generators (LQGs), Small Quantity Generators (SQGs) and Conditionally Exempt Small Quantity Generators (CESQGS) in the Affected Universe by Facility Type and Exhibit ES-2 entitled Aggregate Annual Hazardous Waste Pharmaceuticals Generation by Facility Type for All Facilities (Tons). The contractor shall collect tonnage data, other facility level and industry level data that supports the hazardous waste tons and hazardous waste pharmaceuticals by NAICS code using the methodology consistent with the hazardous waste (HW) generator rule and rewrite the methodology section of chapter 2 and chapter 3 of the finalized and published

Additional information about EPA's quality management system is available at http://www.epa.gov/quality/

¹ The RIA is a required cost and benefit analysis document for EPA's regulations.

Regulatory Impact Analysis of EPA's Proposed Regulations for the Management of Hazardous Waste Pharmaceuticals at Healthcare Facilities. To the extent possible the contractor will not duplicate the effort for the universe and hazardous waste tonnage data for LQGs, SQGs and CESQGs for the healthcare facilities under the HW generator rule universe. The contractor shall update the potentially impacted industries chapter 2 exhibits. The contractor will use ratios of LQGs to SQGs and LQGs to CESQGs that are provided and described in the HW generator rule.

The contractor will contact Massachusetts, Minnesota and New Jersey as well as six other states and try to get updated state facility level and aggregated healthcare facility hazardous waste generator data. The contractor shall collect and update the annual revenues, payroll and number of employees for the potentially to be regulated universe under the final proposed pharmaceuticals rule. The contractor shall look for and summarize any additional relevant studies on the impacts of pharmaceuticals especially hazardous waste pharmaceuticals impact on environmental and human health from improper disposal and/or sewering of pharmaceuticals. The contractor will also use the latest Regulatory Flexibility Small Business Administration's (SBA's) small business thresholds for the RIA.

Task 2: Deliverables

The deliverable under this Task shall be draft and final versions of the updated chapters of the RIA and shall be e-mailed to the Contracting Officer Representative (COR) within 20 days of receiving a Technical Directive (TD). The contractor shall receive up 5 TDs. The contractor shall provide the WAM with separate draft chapters as they are completed and updated and in a later task put all the chapters together as a complete draft RIA. The final deliverable shall be due no later than five working days following contractor receipt of all written COR comments on the draft.

Task 3: Respond to Public Comments on the Proposed Pharmaceuticals Rule RIA

The contractor shall respond to public comments on the Pharmaceuticals Rule RIA in a Memorandum. The contractor shall modify responses to public comments on the pharmaceuticals rule RIA according to WAM direction. The contractor shall provide brief responses in "plain English" to public comments.

- The contractor shall create a way to organize public RIA comments and contractor responses by RIA topic headings.
- The contractor will provide responses to all RIA comments and provide a draft to the WAM.

Task 3: Deliverables

The deliverable under this Task shall be draft and final versions of the completed RIA. The draft deliverable shall be due within 10 working days from COR receipt of the final deliverable (TD or otherwise) under Task 3. The final deliverable shall be due no later than five working days following contractor receipt of all written COR comments on the draft. Briefing packages shall be prepared within 2 Agency work days and e-mailed to the WAM and alternate-WAM.

Task 4: Respond to Public, Workgroup and OP and OMB Comments and Revise the RIA

The contractor shall revise the proposed pharmaceuticals rule RIA based on direction from the WAM. The contractor shall if asked assist with briefing presentations and make editorial and numerical changes to the RIA based on workgroup and public comments.

The contractor shall submit individual draft RIA chapters to the WAM as they are completed and also later combine all of the RIA chapters into a completed draft RIA. Some of the chapters to be provided to the WAM are the following.

Executive Summary

Chapter 1: Introduction

Chapter 2: Potentially Impacted Industries

Chapter 3: Assessment of Costs

Chapter 4: Benefits of the rule

Chapter 5: Summary of Regulatory Benefits & Costs

Chapter 6: Equity Considerations and Other Impacts

The contractor shall assist with the finalization of the final pharmaceuticals rule RIA entitled Regulatory Impact Analysis for EPA's proposed EPA's Proposed Regulations for the Management of Hazardous Waste Pharmaceuticals at Healthcare Facilities. The contractor shall revise the RIA in response to workgroup, WAM and OMB comments. There may be revisions to the methodology and/or numbers in the RIA. Occasionally OMB requests additional sensitivity analysis. The contractor shall compile all of the RIA chapters into one single draft and final RIA. The RIA shall have a table of contents and list of acronyms in the beginning of the RIA. The contractor will also provide an Executive Summary (ES) in the RIA that summarized the findings, costs, benefits and net benefits of the rule similar to the ES in the proposed pharmaceuticals rule RIA. The contractor may also be asked to provide briefing materials for OMB and EPA meetings.

These activities may include, but are not necessarily limited to:

- Additional analyses of the methodology and the models employed in the EA;
- Sensitivity analysis of the number of entities, costs, and/or benefits;
- Preparing briefing packages;
- Providing tables, bullet lists, fact sheets, flow charts, or presentation graphics;
- Drafting a short memo in response to OMB comments regarding how their comments will be handled in regard to the final EA;
 and
- Incorporating editorial comments into the final EA.

Task 4: Deliverables

The deliverable under this Task shall be draft and final versions of the completed RIA Chapters. The draft deliverable chapters shall be due within 10 working days from COR receipt of the final deliverable (TD or otherwise) under Task 4. The completed RIA draft with all of the chapters shall be due in time for management review and FAR. The final deliverable RIA shall be due no later than five working days following contractor receipt of all written COR comments on the draft. Briefing packages shall be prepared within 2 Agency work days and e-mailed to the WAM and alternate-WAM.

Task 4: Update and Finalize the ICR for the Pharmaceuticals Final Rule

The contractor shall design the spreadsheets for the pharmaceuticals final rule RIA to help automate the drafting of the Information Collection Request (ICR) for the rule. The contractor shall write and update and revise the proposed pharmaceuticals rule ICR to satisfy ICR requirements for the final pharmaceuticals rule. Some of the anticipated sections of the ICR are the following.

- 1. Section 1. Identification of the Information Collection
 - a. Title and Number of the Information Collection
 - b. Short Characterization of ICR
- 2. Need for and Use of the Collection
 - a. Need and Authority for the Collection
 - b. Practical Utility and Users of the Data
- 3. Nonduplication, Consultations, and Other Collection
 - a. Nonduplication
 - b. Public Notice
 - c. Consultations
 - d. Effects of Less frequent Collection
 - e. General Guidelines
 - f. Confidentiality
 - g. Sensitivity Questions
- 4. The Respondents and the Information Requested
 - a. Respondents and NAICS Codes
 - b. Information Requested
- 5. The Information Collected-Agency Activities, Collection Methodology, and Information Management
 - a. Agency Activities
 - b. Small Entity Flexibility
- 6. Estimating the Hour and Cost Burden of the Collection
 - a. Estimating Respondent Burden
 - b. Estimating Respondent Costs
 - c. Estimating Agency Burden and Cost
 - d. Estimating State and Local Authority Burden and Costs
 - e. Estimating the Respondent Universe and Total Burden and Costs
 - f. Reasons for Change in Burden

g. Burden Statement

Exhibits

Exhibits 1: Organizations Contacted for Information Supporting the Development of this ICR

Exhibit 2: Estimated Universe of Facilities Affected by the Pharmaceuticals Final Rule

Exhibits 3: Respondent Burden and Cost Estimates by Generator Status

Exhibit 4A: Respondent Burden and Cost Estimates for Large Quantity Generators (LQGs)

Exhibit 4B: Respondent Burden and Cost Estimates for Small Quantity Generators (SQGs)

Exhibit 4C: Respondent Burden and Cost Estimates for Conditionally Exempt Small Quantity Generators

Exhibit 5: Agency Burden and Cost Estimates

Exhibit 6: Burden and Cost Estimates for State and Local Authorities

In addition to the listed sections above the contractor shall add any additional sections as described by the rule writing team, OP and OMB.

Task 5: Programmatic Support

The contractor shall continue to be prepared to provide programmatic support in the area of short-term or quick turnaround technical assistance, analysis, and supporting documents to ORCR for the rule.

Under this task, the contractor shall develop and submit various general support documents and analyses directly or indirectly related to the rule. Examples of such documents/analyses may include, but not be limited to:

- cost or cost savings summary tables addressing impacts of one or more of the regulatory improvement areas;
- brief benefits assessments for one or more of the regulatory improvement areas:
- general or specific briefing packages;
- fact sheets, flow charts, or graphics;

The need for and number of such documents remains uncertain at the time of this WA. The WAM will provide a Technical Directive (TD) designed to clarify the need and scope of such document(s), as necessary. *The contractor shall budget for approximately one (2) TDs under this Task.*

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The man	Comments: The purpose of this amendment is to initiate Work Assignment (WA) 3-8. Phuc Phan is appointed the work assignment manager (WAM) and Rachel Horton as the alternate. WAM. The Level of Effort, (LOE) is in the amount of 158 hours. The statement of work is attached. The contractor shall submit a work plan and cost estimate as it relates to this request.											
Superfund Accounting and Appropriations Data X Non-Superfur										Non-Superfund		
Note: To report additional accounting and appropriations date use EPA Form 1900-69A. SFO (Max 2)												
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Amount (D	ollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)				
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EPA CONTRACT NUMBER EP-W-12-013

Statement of Work

3-08 Work Assignment Number:

<u>Title:</u> Economic Analysis and Related Support for: **Improvements to the Hazardous Waste** Generator Regulatory Program, and Associated RCRA Work

Work Assignment Manager (WAM): Phuc Phan

Alternate WAM: Rachel Horton

> **ERAS/ORCR/OSWER** Address:

Mail Code 5305P

1200 Pennsylvania Ave. N.W. Washington, D.C. 20460

(703) 306-1013 Telephone:

(703) 308-5268 (front office) (703) 308-7903 (fax)

Work Assignment Alternate Manager: Rachel Horton

> Address: ERAS/ORCR/OSWER

> > Mail Code 5305P

1200 Pennsylvania Ave. N.W. Washington, D.C. 20460

Telephone:

(703) 305-0894 (703) 308-5268 (front office) (703) 308-7903 (FAX)

Period of Performance: CO signature through April 29, 2016.

PURPOSE AND SCOPE OF THIS WORK ASSIGNMENT AMENDMENT:

The purpose of this Work Assignment (WA) is to continue the work on finalizing the economic analysis (EA). The scope of this WA may include: responding to the WAM or the alternate WAM, Office of Management and Budget (OMB), Office of Policy (OP), and the workgroup. It may include expanded analytical methodology; alternative baseline adjustments; ongoing new and refined data collection and quality control; analytical model expansion; alternative options/sensitivity analyses; information collection request (ICR) development, and continued EA document preparation and revisions. The primary focus of this WA is to incorporate comments and suggestions to finalize the EA and ICR.

Finally, this WA includes the continued potential need for preparation of emergency turnaround assessments, general supporting materials, briefings, general project coordination, and ongoing communication/outreach to the WAM and alternate WAM.

WORK STATEMENT:

Task 1. Work Plan, Progress Reports and Budget

Within twenty (20) days of receipt of this WA, the contractor shall deliver a work plan. This plan shall include a proposed level of effort, budget, schedule of tasks, and schedule of deliverables. A cost proposal shall accompany this work plan.

All data collection, assessment, and quality issues associated with this WA shall adhere to EPA data quality guidance and requirements, as established in EPA Order 5360.1A2, EPA Manual 5360.A1, and OSWER's and ORCR's Quality Management Plans. See: http://www.epa.gov/quality/qa_docs.html

As part of the monthly progress reports for this WA, the contractor shall provide a summary of all data collection and quality control activities conducted during each month.

No confidential business information (CBI) shall be collected or used in conjunction with this WA. However, proprietary data may be used following written approval from the WAM.

This WA includes no limited travel for the contractor. However, travel remains approved under the prior Amendment.

Deliverable(s) and Schedule:

Work Plan and Budget within allotted time frame identified above.

Task 2: Programmatic Support

The contractor shall continue to be prepared to provide programmatic support in the area of short-term or quick turnaround technical assistance, analysis, and supporting documents to ORCR for the rule.

Under this task, the contractor shall develop and submit various general support documents and analyses directly or indirectly related to the rule. Examples of such documents/analyses may include, but not be limited to:

- cost or cost savings summary tables addressing impacts of one or more of the regulatory improvement areas;
- brief benefits assessments for one or more of the regulatory improvement areas;
- general or specific briefing packages;
- fact sheets, flow charts, or graphics;

The need for and number of such documents remains uncertain at the time of this WA. The WAM will provide a Technical Directive (TD) designed to clarify the need and scope of such document(s), as necessary. The contractor shall budget for approximately two (2) TDs under this Task.

Work under this task shall build upon, but not duplicate work conducted under WA 2-08.

Deliverable(s) and Schedule:

DELIVERABLES	DUE DATES
Development of quick-turnaround support documents	<u>Draft</u> : Three Agency working days
and analyses related to the rule:	from receipt of TD and all supporting
	information.
To be defined in the TD (e.g., briefing package, fact	
sheet)	Final: Three Agency working days
	from receipt of all written WAM
	comments on draft.

Task 3: Responding to Comments to Finalize the RIA

EPA is not expecting to receive a lot of comments from Office of Policy, OEI, OMB, and public comments because some of the proposed requirements are voluntary, which provide more flexibility for the regulated industries to comply with existing regulations. However, the contractor might have to revise costs, economic impacts, benefits, small entity impacts, information collection request (ICR), and related technical and supporting analyses necessary to sustain the Agency's promulgation of the rule: "Improvements to the Hazardous Waste Generator Regulatory Program, and Associated RCRA Work."

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		Work Plan	Approval					From (04/30/2	2015 To	04	/29/2016
The p	Comments: The purpose of this amendment is to approve and accept the contractor's work plan/cost Estimate dated 05/20/2015 with a LOE of 158 hours and \$15,788.88 $(b)(4)$ cost $(b)(4)$ fee). The contractor is not allowed to go over the approve ceilings without the approval of the Contracting Officer.											
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Project Officer Name Shannon Stu	urgeon			Brar	nch/Mail Co	de:				
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The und	Comments: The purpose of this work assignment is to add additional level of effort (LOE) of 365 hours for on-going support under this work assignment. The total LOE for the work assignment is now 523 hours. The statement of work is attached. The contractor shall submit a work plan/cost estimate in response to this request.													
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EPA CONTRACT NUMBER EP-W-12-013

Statement of Work

3-08 Work Assignment Number:

<u>Title:</u> Economic Analysis and Related Support for: **Improvements to the Hazardous Waste** Generator Regulatory Program, and Associated RCRA Work

Work Assignment Manager (WAM): Chris McMinimy

> Address: ERAS/ORCR/OSWER

Mail Code 5305P

1200 Pennsylvania Ave. N.W.

Washington, D.C. 20460

Telephone: (703) 308-0105

(703) 308-5268 (front office)

(703) 308-7903 (fax)

Work Assignment Alternate Manager: Rachel Horton

> Address: ERAS/ORCR/OSWER

Mail Code 5305P

1200 Pennsylvania Ave. N.W.

Washington, D.C. 20460

Telephone: (703) 305-0894

(703) 308-5268 (front office) (703) 308-7903 (FAX)

Period of Performance: CO signature through April 29, 2016.

PURPOSE AND SCOPE OF THIS WORK ASSIGNMENT AMENDMENT:

The purpose of this Work Assignment (WA) is to revise the approved work assignment to add X hours of additional LOE. The LOE will provide funding for the contractor to incorporate revised data on the universe of potentially affected facilities into the RIA and ICR. The work assigned in this amendment builds upon the work already conducted under the existing work assignment 3-08 task 3.

WORK STATEMENT:

Task 1. Work Plan, Progress Reports and Budget

Within twenty (20) days of receipt of this WA, the contractor shall deliver a work plan. This plan shall include a proposed level of effort, budget, schedule of tasks, and schedule of deliverables. A cost proposal shall accompany this work plan.

All data collection, assessment, and quality issues associated with this WA shall adhere to EPA data quality guidance and requirements, as established in EPA Order 5360.1A2, EPA Manual 5360.A1, and OSWER's and ORCR's Quality Management Plans. See: http://www.epa.gov/quality/qa_docs.html

As part of the monthly progress reports for this WA, the contractor shall provide a summary of all data collection and quality control activities conducted during each month.

No confidential business information (CBI) shall be collected or used in conjunction with this WA. However, proprietary data may be used following written approval from the WAM.

This WA includes no limited travel for the contractor. However, travel remains approved under the prior Amendment.

Deliverable(s) and Schedule:

Work Plan and Budget within allotted time frame identified above.

Task 4: Update Universe to Finalize the RIA

The contractor shall revise the universe of facilities that may be potentially affected by the proposed rule using updated data provided by the WAM. The contractor shall revise and resubmit the potentially impacted universe, costs, economic impacts, benefits, small entity impacts, and related technical and support analyses using the updated data. Specific instructions will be provided by the WAM by technical direction.

Task 5: Update Information Collection Request

The contractor shall revise the ICR and incorporate the updated universe of facilities that may be potentially affected by the proposed rule. The contractor might have to revise the ICR to incorporate changes to the rule preamble and text. Specific instructions will be provided by the WAM by technical direction.

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Comments: The purpose of this amendment is to approve the contractor's work plan dated $12/21/15$ with a level of effort (LOE) of 365 hours and \$35,027.65 (b)(4) cost (b)(4) fee). The total is now \$50,816 (b)(4) cost (b)(4) fee) and 523 LOE hours. The contractor is not allowed to go over the approved ceilings without the approval of the Contracting Officer.														
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assignment manager (WAM). The	e Level of Effort, (LC	DE) is in amoun	t of 760 h	ours. The	statement of w			
The contractor shall submit	a work plan and cost	estimate as it	relates t	o this re	quest.			
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Contract # : EPW 12 013 Statement of Work W A 3-10

Title: eEnterprise Scoping Analyses in OSWER

Contracting Officer's Representative: Name: David Nicholas

202-566-1927

Address: OSWER/PARMS (5103t) Fax No: 202 566-1933

1200 Pennsylvania, NW, Washington, DC 20460

BACKGROUND, PURPOSE AND SCOPE

The Government Performance and Results Act (GPRA) of 1993 and GPRA Modernization Act of 2010 hold all federal agencies accountable for how they use their resources to achieve results. It requires: (1) strategic planning, (2) the development of measures to assess program performance and progress, (3) that information is reported to the public, and (4) that agencies develop a schedule of planned and completed program evaluations.

Assessing the benefits of modernizing our national system of environmental protection, in coordination with our state, local, and tribal partners is an essential component to understanding our progress towards agencywide GPRA goals and objectives. The initiative to modernize the way environmental results are monitored, reported and assessed is known as eEnterprise.

eEnterprise is an initiative between States and EPA to improve environmental outcomes through maximizing the use of advanced monitoring and technology; optimizing program operations; increasing transparency; and to dramatically enhance service to the regulated community and the public. This initiative will expand the use of advance monitoring technology in research, regulations, and inspections so that government, regulated entities and the public will have better information on sources of pollutants and environmental conditions. This statement of work covers the support needed to assess the benefits of taking this new approach and describe the positive impacts and costs in both quantitative and qualitative terms.

To ensure state perspectives are included, EPA and the Environmental Council of States (ECOS) formed a Working Group in June 2012 to collaboratively pursue electronic reporting between regulated entities and environmental government regulators. However, electronic reporting is only one part of a much larger set of opportunities and challenges that need to be addressed as we seek to modernize our approach to environmental protection using advances in both emissions/pollutant monitoring and information technology. Further, on December 5, 2012 the President of ECOS and the US EPA Deputy Administrator signed a joint statement confirming the commitment of the States and EPA to collaboratively govern eEnterprise.

In this larger initiative, called eEnterprise, regulated entities could electronically conduct business transactions with the government: submitting permit applications,

updating financial assurance documentation, and reporting emission and pollutant discharge data. The tools/systems that support this should be "smart" to help entities understand their regulatory obligations, eliminate duplicative entry of information and efficiently support electronic signature requirements consistent with proposed EPA and state regulations. Quantifying and describing these beneficial impacts is a necessary step in managing the eEnterprise initiative and will form the core of this statement of work's tasks.

OSWER is leading an agencywide team along with state partners to examine the potential barriers to broader adoption of electronic permitting systems. States already have experience with new approaches to permitting that evolve the current paper-intensive process to a web-based system enabling faster reviews and approvals with added transparency and certainty of results for all stakeholders. As a scoping project under the jointly governed eEnterprise initiative, this work will inform decisions whether to undertake additional analysis, including cost/benefit assessment on potential solutions described in this scoping report.

This work builds on previous tasks and the COR is authorized to provide written technical direction to the Contractor (with a courtesy copy to the Contracting Officer and Project COR) to clarify requirements already specified in this Statement of Work.

Work on this Call Order shall begin on date of award and end April 29, 2016. Work under this Call Order applies to task IV of the BPA SOW.

TASK 1: Analysis of OSWER Program Reporting Burden

- 1-1 The contractor shall analyze the current conditions of state's use of electronic permitting application systems for all media permitting programs delegated by EPA. The contractor shall use existing inventory lists provided by EPA as a starting point and summarize the findings in a 3-5 page report.
- 1-2 The contractor shall assist the EPA/State team in gathering input from states with ePermitting systems in conference calls and take notes. The contractor shall participate and take notes in outreach sessions to key state program associations such as ASTSWMO and similar meetings convened by the EPA/State team. The contractor shall provide draft summary reports of the input gathered to date per COR technical direction to the EPA/State team for review and make revisions as necessary on a continuing basis until the completion of Task 4 (see below).

Deliverables and Schedule Under Task 1

- 1-1 Summary report of baseline conditions in ePermitting in states.
 - a. Draft report 14 days after the COR sends technical direction
 - b. Final report 7 days after COR sends review comments
- 1-2 Summaries of state program input and state association input
 - a. Draft report 21 days after the COR sends technical direction
 - b. Final report 7 days after COR sends review comments

TASK 2: Analysis of Barriers to Broader ePermitting Adoption

2-1 In consultation with the COR and EPA/State team, the contractor shall develop a frequency chart arranged by categories originally drafted by the team and populate it with findings from the notes drafted in Task 1. The contractor will develop companion narrative to the chart and analyze any emerging trends in the data.

Deliverables and Schedule Under Task 2

- 2-1 Frequency Chart and Narrative
 - a. Draft chart 21 days after the COR sends technical direction
 - b. Final chart and narrative 7 days after COR sends review comments

TASK 3: Data Needs for Cost/ Benefit Assessment and Emerging Solutions

3-1 The contractor shall identify data needs to conduct cost/benefit assessments based on trends observed in the data collected in Tasks 1 and 2. The contractor shall identify emerging solutions to the barriers to broader ePermitting adoption with associated data needs if a formal cost/benefit assessment were to be undertaken as a next step for further study. The contractor shall provide a draft report and revise into a final 2-3 page report as directed by the COR.

Deliverables and Schedule Under Task 3

- 3-1
- a. Draft report 5 days after the COR sends technical direction
- b. Final report 5 days after COR sends review comments

Task 4: Drafting of Final Report

4-1 The contractor shall assemble the summary report elements from prior tasks into a final report for presentation to the eEnterprise Leadership Council.

Deliverables and Schedule Under Task 4

- 4-1
- a. Draft report 5 days after the COR sends technical direction
- b. Final report 5 days after COR sends review comments

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Contract # : EPW 12 013 Statement of Work W A 3-10

Title: eEnterprise Scoping Analyses in OSWER

Contracting Officer's Representative: Name: David Nicholas

202-566-1927

Address: OSWER/PARMS (5103t) Fax No: 202 566-1933

1200 Pennsylvania, NW, Washington, DC 20460

BACKGROUND, PURPOSE AND SCOPE

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Task 1: Development of Workplan

The contractor shall develop and provide a workplan for this project no later than 10 working days after receipt of the work assignment. The workplan shall describe all required tasks and associated deliverables.

Deliverables and Schedule

Task 1. No later than 10 working days after receipt of the work assignment.

TASK 2: Analysis of OSWER Program Reporting Burden

- 2-1 The contractor shall analyze the current conditions of state's use of electronic permitting application systems for all media permitting programs delegated by EPA. The contractor shall use existing inventory lists provided by EPA as a starting point and summarize the findings in a 3-5 page report.
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completion of a final report.

Deliverables and Schedule Under Task 2

- 2-1 Summary report of baseline conditions in ePermitting in states.
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 - a. Draft report 21 days after the COR sends technical direction
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TASK 2-3: Analysis of Barriers to Broader ePermitting Adoption

2-3 In consultation with the COR and EPA/State team, the contractor shall develop a frequency chart arranged by categories originally drafted by the team and populate it with findings from the notes drafted in Task 1. The contractor will develop companion narrative to the chart and analyze any emerging trends in the data.

Deliverables and Schedule Under Task 2-3

- 2-3 Frequency Chart and Narrative
 - a. Draft chart 21 days after the COR sends technical direction
 - b. Final chart and narrative 7 days after COR sends review comments

TASK 2-4: Data Needs for Cost/ Benefit Assessment and Emerging Solutions

2-4 The contractor shall identify data needs to conduct cost/benefit assessments based on trends observed in the data collected in Tasks 1 and 2. These data needs, once identified will be specified in the final report. The contractor shall provide a draft list of these data needs as directed by the COR.

Deliverables and Schedule Under Task 2-4

- 2-4
- a. Draft list 5 days after the COR sends technical direction
- b. Final list 5 days after COR sends review comments

Task 2-5: Drafting of Final Report

2-5 Contractor shall assemble the summary report elements from prior tasks into a final report for presentation to the eEnterprise Leadership Council.

Deliverables and Schedule Under Task 2-5

- 2-5
- a. Draft report 5 days after the COR sends technical direction
- b. Final report 5 days after COR sends review comments



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